

Congress of the United States
Washington, DC 20515

October 23, 2020

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Azar:

We write today concerning the politicization of the search for a coronavirus disease of 2019 (COVID-19) vaccine. We know a safe, effective, and trusted COVID-19 vaccine will be a critical tool to contain this pandemic. To ensure its success, the American people must be able to have confidence that science, not politics, is driving all COVID-19 vaccine authorization or approval decisions. Unfortunately, due to the Trump Administration's actions undermining science throughout the COVID-19 pandemic response, including the pursuit of vaccines, we are compelled to urge you to allow the U.S. Food and Drug Administration (FDA) to do its job and to protect the scientific integrity of the COVID-19 vaccine approval process.

We appreciate FDA career staff's stewardship of the COVID-19 vaccine process to date. We are further encouraged by FDA's issuance of additional guidance on October 6 on the Emergency Use Authorization (EUA) process for COVID-19 vaccines.¹ This guidance comes at a crucial time in which clarity and transparency regarding the vaccine approval process is imperative to assure the American people that an authorized COVID-19 vaccine will be safe.

The manufacturers pursuing COVID-19 vaccine candidates have committed to putting forward a vaccine only after it has been thoroughly vetted. In September, nine companies joined in an unprecedented pledge that potential vaccines for COVID-19 will be developed "in accordance with high ethical standards and sound scientific principles."² Further, the four companies with vaccine candidates currently in phase 3 clinical trials have released their trial protocols, an important step towards transparency.

We are extremely concerned, however, by the Administration's actions and communications that undermine FDA leadership and industry transparency—sowing distrust among the American people. According to reports, FDA's EUA guidance was delayed for weeks by the White House, which reportedly tried to block its release.³ This follows the pattern

¹ U.S. Food and Drug Administration, *Emergency Use Authorization for Vaccines to Prevent COVID-19: Guidance for Industry* (Oct. 2020) (guidance document).

² *Biopharma Leaders Unite to Stand with Science*, Business Wire (Sept. 8, 2020).

³ *White House Blocks New Coronavirus Vaccine Guidelines*, New York Times (Oct. 5, 2020).

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of President Trump’s repeated claims—contradicting his own scientists and industry executives—that a COVID-19 vaccine will be available by Election Day, including falsely accusing FDA of being part of a “deep state” plot to delay a vaccine.⁴ His attacks continued following FDA’s issuance of the EUA guidance in tweeting, “New FDA Rules make it more difficult for them to speed up vaccines for approval before Election Day. Just another political hit job!”⁵

As we have confronted the COVID-19 pandemic for nine months, more than 7.5 million Americans have had the virus and 211,000 of them have lost their lives. Millions of Americans face unemployment and have lost their health insurance, and families are juggling childcare and virtual classrooms. The lives of Black and Latino people, Native Americans, the elderly, and others more vulnerable to COVID-19 are especially on the line as it continues to spread across the country.

We all want a COVID-19 vaccine as soon as possible as another tool to help contain the pandemic and ease the nation’s suffering, but any vaccine made available must be safe, effective, accessible, and trusted by the American people. Following science and public health expertise is the only way we will achieve this success.

We urge you to allow the scientific experts at FDA to do their jobs, to adhere to the guidance they have developed prior to making any COVID-19 vaccine available for use, and to ensure all COVID-19 vaccine decisions are free from political interference.

Sincerely,


Frank Pallone, Jr.
Member of Congress


Diana DeGette
Member of Congress

Sean Casten
Member of Congress

Gilbert R. Cisneros, Jr.
Member of Congress

David Price
Member of Congress

Mike Doyle
Member of Congress

⁴ *Trump without evidence accuses ‘deep state’ at FDA of slow-walking coronavirus vaccines and treatments*, Washington Post (Aug. 22, 2020).

⁵ President Donald J. Trump (@realDonaldTrump), Twitter (Oct. 6, 2020, 9:09 PM) (twitter.com/realDonaldTrump/status/1313647605134614529?s=20).

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Member of Congress

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Member of Congress

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